EPA Registration # 82415-2 Volume 2



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON D.C., 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

CERTIFIED MAIL

AUG 2 0 2009

Fuji Chemical Industries, LTD Delta Analytical Corporation 12510 Prosperity Drive, Ste 160 Silver Spring, MD 20904

Subject:

Inquiry Into the Possible Presence of Silver Measuring Between 1 and approximately

100 Nanometers in Registered, Silver-Based Pesticide Products

Dear Sir/Madam:

The United States Environmental Protection Agency (EPA) understands that some registered silver-based pesticide products may contain silver in a form that is measurable in nanometers. For purposes of this particular letter and request, EPA is specifically interested in determining if your silver-based pesticide product contains any amount of silver in any form having a dimension that measures between 1 and approximately 100 nanometers [hereinafter referred to as "nanosilver"]. Please be advised that the specified size range is subject to change in the future as new information becomes available. Accordingly, the Agency reserves the right to revisit and change the specified size range if necessary.

Your company has the following currently registered silver product(s):

Registration Number	Registration Name
82415-1	BACTEKILLER AC
82415-2	BACTEKILLER AZ
82415-8	BACTEKILLER G

The Agency is requesting the following information from the product(s) listed above:

- A statement as to whether (or not) your registered, silver-based pesticide product(s) contain(s) any amount of nanosilver.
- If your product(s) does/do contain nanosilver, any existing information not previously
 provided to the Agency that characterizes the size and size distribution of such silver as
 measured in nanometers, as well as any information not previously provided to the
 Agency that describes the manufacturing process used to produce the silver in the size
 range specified above.
- If your product(s) is/are to be used for an end-use formulation that contain(s) a composite (the active ingredient comprised of nanosilver, plus a carrier [e.g., silica or sulfur], that

forms a matrix complex), any existing information not previously provided to the Agency that characterizes the size and size distribution of the composite.

If your product(s) does/do contain nanosilver, any existing information not previously
provided to the Agency that addresses the effects of exposure to the nanosilver on
humans or nontarget species, and/or on the levels of potential human and environmental
exposure.

Please note that it is EPA's position that the information requested above is reportable under FIFRA section 6(a)(2), which requires the reporting of any factual information regarding unreasonable adverse effects on the environment. As codified in EPA's regulations setting forth the reporting requirements for risk/benefit information under section 6(a)(2), registrants are required to submit information:

"if the registrant knows, or reasonably should know, that if the information should prove to be correct, EPA might regard the information alone or in conjunction with other information about the pesticide as raising concerns about the continued registration of a product or about the appropriate terms and conditions of registration of a product."

40 CFR §159.195(a).

In accordance with your FIFRA section 6(a)(2) obligation, therefore, EPA seeks receipt of the information set forth above, to the extent you have such information, within 30 days from the date of receipt of this letter. Please note that a failure to comply with the requirements of FIFRA section 6(a)(2) is considered a violation of FIFRA sections 12(a)(2)(B)(ii) and 12(a)(2)(N), and could result in actions for civil penalties and/or criminal penalties under FIFRA section 14.

If you have any questions concerning this letter, please contact Marshall Swindell at (703) 308-6341 or Demson Fuller at (703) 308-8062.

Sincerely,

Joan Harrigan-Farrelly, Director

Antimicrobials Division

Office of Pesticide Programs

Material to be added to a Mini-Jacket (in the case where an e-Jacket exists)

Reg. No.	82415-2
-	

Send to SIG: check box

This material is:

- € New stamped-accepted label
- € New CSF
- € Notification
- € Final Printed Label
- € Other:

Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).

Reviewer's Name: Martha Jerry

Date: 6/29/06

CODING FORM FO	DDE # 792685 R APPLICATIONS			N/AMENDM
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APR 11 2006

Fuji Chemical Industries, Ltd 15-27 Edobori-1-Chrome, Nishi-Ku Osaka 550-0002, Japan

AGENT: Ciba Specialty Chemicals 4090 Premier Drive High Point, N. C. 27265

Attention: Tom Barber

Subject: Bactekiller AZ

EPA Registration No. 82415-2 Notification Dated March 22, 2006

This will acknowledge receipt of your notification to correct a typographical error in the ingredients statement, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

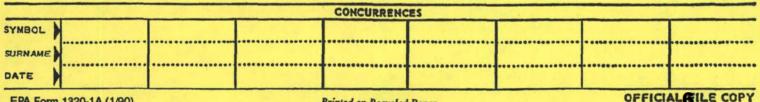
If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,

Marshall Swindell

Product Manager (33)

Regulatory Management Branch 1 Antimcrobials Division (7510C)



EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL GILE COPY

Regulatory Services



March 22, 2006

via Federal Express

US Environmental Protection Agency Document Processing Desk (NOTIF) Office of Pesticide Programs (7504C) Room 266A, Crystal Mall 2 1801 South Bell Street Arlington, Virginia 22202-4501

Attention: Mr. Marshall Swindell (PM33)

Re: Bactekiller® AZ, EPA Reg. No. 82415-2

Dear Mr. Swindell:

On behalf of our client, Fuji Chemical Industries, Ltd., enclosed please find a Notification in accordance with PR 98-10 to correct a typographical error in the ingredients statement for the level of Zinc and Other Ingredients. The current CSF for this product is correct and there are no other changes; this is strictly a typographical error correction to the label.

Please note that this product was officially transferred to Fuji Chemical Industries, Ltd. from Kanebo Ltd. (old EPA Reg. No. 59824-2); the new EPA Reg. No. 82415-2 was assigned on September 12, 2005. The typographical error subject of this notification was made by Kanebo during their last label amendment to comply with the precautionary statements according to PR 2001-1.

Enclosed with this cover letter are the following documents:

- Application Form 8570-1
- Corrected label 1 copy (changes highlighted)
- Authorized agent letter allowing Ciba Specialty Chemicals to represent Fuji Chemical Industries, Ltd.

Should you have any questions or wish further information, do not hesitate to contact me directly at (336) 801-2603.

Respectfully,

Tom Barber

Authorized Agent for Fuji Chemical Industries, Ltd.

4090 Premier Drive High Point, NC 27265

Tel. 336-801-2603 Fax 336-801-2056

5. Date

March 22, 2006

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

Thomas Barber

White - EPA File Copy (Original)

Yellow - Applicant Copy

Fuji Chemical Industries, Ltd.

Alte Building Higobashi
15-27, Edobori 1-Chome, Nishi-Ku, Osaka 550-0002, Japan
Phone: +81(6)6444-3928 Fax: +81(6)6444-3916

March 22, 2006

Mr. Marshall Swindell, PM-33
Office of Pesticide Programs (APPL)
Registration Division (7504C)
Environmental Protection Agency (EPA)
401 M Street, SW
Washington, DC 20460-0001

SUBJECT: Fuji Chemical Industries, Ltd. Zeolite Product Registration

Dear Mr. Swindell:

and state registrations.

Fuji Chemical Industries, Ltd. ("Fuji") is designating Ciba® Expert Services, Ciba Specialty Corporation, 540 White Plains Road Tarrytown, New York 10591 as our agent in the submittal of their Bactekiller line of Zeolite products for EPA

Ciba® Expert Services has authority to act as our agent regarding these

registrations.

Sincerely,

Hajime Takanashi Managing Director

Fuji Chemical Industries, Ltd.

\$EPA	Se before completing form Uni Environmental	ted States		Regi	stration endment	OPP Identifier Numbe
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			Pesticide – Sect	ion I		
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Contact Person (Complete	e items directly below for		ndividual to be contac			
Name Thomas Barber					Telephone No. (I (336) 801-2603	nclude Area Code)
I certify that the statements I I I acknowledge that any knowi	have made on this form an	ertification d all attachments	thereto are true, accu		plete.	Date Application Received
2. Signature		3. Title Authoriz	ed Agent for Fuji Che	emical Industri	ies, Ltd.	(Stamped)
1 Typed Name		5. Date			••	
Typed Name Thomas Barber		March 2	2, 2006			
Thomas Barbor						

BACTEKILLER ® AZ

Silver-Zinc Zeolite

An antimicrobial powder for commercial and industrial use designed to be incorporated into various materials during varying stages of the manufacturing process to preserve the integrity of the materials.

For more details of the various materials refer to the Technical Bulletin for uses of Bactekiller® AZ.

 Active ingredient:
 3.5%

 Silver (as elemental)
 6.5%

 Zinc (as elemental)
 6.5%

 Inert ingredient:
 20.0%

 Total
 100.0%

KEEP OUT OF REACH OF CHILDREN CAUTION

Net Weight: Lot No.:

FUJI CHEMICAL INDUSTRIES, LTD. 15-27, EDOBORI 1-CHOME NISHI-KU, OSAKA 550-0002, JAPAN

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

See Technical Bulletin for more detailed use information

BACTEKILLER * AZ is a silver zinc zeolite powder designed to be incorporated into various materials at various stages of their manufacturing process to impart antimicrobial properties to the manufactured materials. The powder can be incorporated into the materials as an integral part of the finished products throughout their entire thickness or as a film over the surfaces of the manufactured materials, depending on the particular method of manufacture of the finished materials and needs of the manufacturer.

BACTEKILLER® AZ may be incorporated into the following materials at specified Maximum Inhibitory Concentrations (MIC) on a dry weight of finished products.

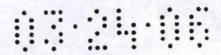
Application	MIC
Plastic Film: (non-food use only and no water pipes) polypropylene, polyvinyl chloride, polyacetate, and polyester	1.50%
Paints: (water base and solvent base)	1.50%
Paper coating: (non-food packaging paper, no food contact) (not for paper production use)	1.50%
Adhesive: (non food contact) plywood adhesives	2.00%
Synthetic Fibers: polyester, nylon, polypropylene, Acrylic, and rayon	1.50%
Pigments: dyestuffs and inks	1.00%
Textile Finishing and Manufacturing	0.75%

STORAGE AND DISPOSAL

Storage and Disposal: Do not store in areas accessible to children. Do not store in place where food or feed may come in contact with the product. Keep away from direct sunlight. Unused material should be disposed of on site or an approved waste disposal facility.

Container Disposal: Empty container thoroughly and rise with water. Dispose in regular trash collection.

BACTEKILLER® is a trademark of Fuji Chemical Industries, Ltd. EPA Registration No. 82415-2



PRECAUTIONARY STATEMENTS KEEP OUT OF REACH OF CHILDREN CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Caution: May be harmful if swallowed. Avoid contact with skin, eyes or clothing. Avoid contamination of cooking utensils and food preparation surfaces.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Keep out of any natural body of water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge unused material into natural bodies of water unless in accordance with a NPDES permit.

FIRST AID:

Have the product label or container with you when calling a poison control center or doctor, or going for treatment.

IF SWALLOWED	 Call a poison control center or doctor immediately for treatment advice. Have person to sip a glass of water if able to swallow.
	 Do not induce vomiting unless told to do so by a person control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor immediately for treatment advice.
IFINHALED	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor immediately for treatment advice.
IF IN EYES	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor immediately for treatment advice.

In case of emergency, call the National Pesticide Telecommunications Network at 1-800-858-7378 Phone: Fuji Chemical Industries, Ltd. (81)-6-6444-3928, Osaka, Japan

Material to be added to a Mini-Jacket (in the case where an e-Jacket exists)

Reg. No. 82415-Z
Send to SIG: check box □
This material is:
□ New stamped-accepted label □ New CSF □ Notification □ Final Printed Label □ Other:
Instructions: Attach this notice on top of the material. It must be clipped all together and then should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).
Reviewer's Name: K. Leavy
Phone: 308-6237 Division: 40
Date: 8/3/106

DECISION PKG. NO.	2828	SUBM.	DUE DATE 9/24/00	6
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RESPONSE CODE 1300

<u>~</u>	KAREN MARTHA PORTIA
7	PLEASE MAKE AN ACTION CODE SHEET PLEASE PROCESS THIS SUBMISSION: CODE 502 DUE 9/24/04 BRING THIS SUBMISSION TO THE NEXT PRIA MTG
	RETURN THE DATA THAT FAILED 86-5 FORMATTING
	PLEASE UPDATE YOUR PRIA NOTEBOOK TO REFLECT THIS ACTION PLEASE TRANSFER THIS FILE FROM MY NAME TO YOURS
	PLEASE ROUTE THIS TO THE APPROPRIATE SCI GROUP ASAP PLEASE MAKE THE CORRECTIONS NOTED IN THE ATTACHMENT
	CLOSE OPPIN RECORD WITH THE RESPONSE CODE/DATE.
	PLACE ALL PAPERWORK IN ORDER AND PLACE IN FILE PLACE ALL PAPERWORK IN ORDER AND ADD TO THE ELECTRONIC FILE
	PLEASE MAIL THE LETTER THIS IS A PRIA. PRINT THE SHEET SHOWING THE FEE WAS PAID/WAIVED,
	THEN DATE THE SHEET AND SIGN IT. THIS SHEET GOES INTO THE FILE JACKET. ADD THE SCIENCE REVIEWS TO THE LETTER BEING MAILED.
	SEND TO SIG
	ADD COPY OF LETTER AND LABEL TO THE READER'S FILE
	PLEASE COPY YOUR LETTER TO THE AD STORAGE AREA
	PLEASE RETURN THIS SHEET WHEN DONE

DATE COMPLETED _

7/5/2006 18:03 M.SWINDELL



June 21, 2006

Mr. Marshall Swindell (PM33)
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U. D. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

RE: Bactekiller AZ

EPA Registration No. 82415-2

PR Notice 98-10

Dear Mr. Swindell:

In reference to your letter dated April 11, 2006 and on behalf of our client, Fuji Chemical Industries, Ltd., enclosed is the amended and approved FIFRA label for reconciliation for the product Bactekiller AZ. Please place in our file.

Should you have any questions or wish further information, please contact me directly at (336) 801-2600.

Your assistance is greatly appreciated.

Respectfully,

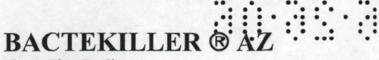
Joyce Dunn

Regulatory Services Specialist

Enclosure

4090 Premier Drive High Point, NC 27265

Tel. 336-801-2600 Fax 336-801-2056



Silver-Zinc Zeolite

An antimicrobial powder for commercial and industrial use designed to be incorporated into various materials during varying stages of the manufacturing process to preserve the integrity of the materials.

For more details of the various materials refer to the Technical Bulletin for uses of Bactekiller® AZ.

Active ingredient:

 Silver (as elemental)
 3.5%

 Zinc (as elemental)
 6.5%

 Inert ingredient:
 .90.0%

 Total
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KEEP OUT OF REACH OF CHILDREN CAUTION

Net Weight: Lot No.:

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

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BACTEKILLER® AZ may be incorporated into the following ma Inhibitory Concentrations (MIC) on a dry weight of finished products:

Application	MIC
Plastic Film: (non-food use only and no water pipes) polypropylene, polyvinyl chloride, polyacetate, and polyester	1.50%
Paints: (water base and solvent base)	1.50%
Paper coating: (non-food packaging paper, no food contact) (not for paper production use)	1.50%
Adhesive: (non food contact) plywood adhesives	2.00% :
Synthetic Fibers: polyester, nylon, polypropylene, Acrylic, and rayon	1.50%
Pigments: dyestuffs and inks	1.00%
Textile Finishing and Manufacturing	0.75%

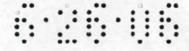
STORAGE AND DISPOSAL

Storage and Disposal: Do not store in areas accessible to children. Do not store in place where food or feed may come in contact with the product. Keep away from direct sunlight. Unused material should be disposed of on site or an approved waste disposal children. Dispose in regular trash.

Container Disposal: Empty container thoroughly and rise with water. Dispose in equilar trash collection.

FUJI CHEMICAL INDUSTRIES, LTD. 15-27, EDOBORI 1-CHOME NISHI-KU, OSAKA 550-0002, JAPAN

BACTEKILLER® is a trademark of Fuji Chemical Industries, Ltd. EPA Registration No. 82415-2



PRECAUTIONARY STATEMENTS KEEP OUT OF REACH OF CHILDREN CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Caution: May be harmful if swallowed. Avoid contact with skin, eyes or clothing. Avoid contamination of cooking utensils and food preparation surfaces.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Keep out of any natural body of water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge unused material into natural bodies of water unless in accordance with a NPDES permit.

FIRST AID:

IF SWALLOWED

Have the product label or container with you when calling a poison control center or doctor, or going for treatment.

Call a poison control center or doctor immediately for treatment

Call a poison control center or doctor immediately for treatment

	 advice. Have person to sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a person control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor immediately for treatment advice.

	advice.
IF INHALED	 Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor immediately for treatment advice.
IF IN EYES	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

advice.

In case of emergency, call the National Pesticide Telecommunications Network at 1-800-858-7378.

Phone: Fuji Chemical Industries, Ltd. (81)-6-6444-3928, Osaka, Japan

